

Appl. No. : 09/996,020
Filed : November 27, 2001

REMARKS

The 35 USC 112 Rejection

Claims 45-56, and 100-106 were rejected under 35 USC 112, second paragraph as indefinite for lacking antecedent basis. Claims 45 and 100 were amended and thus this rejection is now moot. Withdrawal of the rejection is believed to be in order.

The 35 USC 102 Rejections

Claims 57-63, 70-80, 83-86, 90-109 and 113 were rejected under 35 USC 102(b) as anticipated by Inoue et al. (US Patent No. 4,514,574). Applicants respectfully traverse this rejection.

Inoue describes treating mixtures of isomers with a supercritical fluid (SCF) so as to selectively dissolve one of the isomers. After one of the isomers is dissolved, the fluid is expanded to retrieve the extracted isomer. This is a process for separating components of a mixture by passing an SCF over a static bulk of a mixture to be separated.

Claim 57 and its dependents (claims 58-63, 70-80 and 83-86), claim 90 and its dependents (claims 91-99), and claim 100 and its dependents (claims 101-106) claim a method for forming particulates where a substrate is surrounded by a coating layer. The substrate is contacted with a coating material and a supercritical fluid to form the particulates. Inoue does not relate to the production of coated particles; Inoue's products do not comprise a substrate core surrounded by a coating layer. Thus his teachings are not relevant to present claims 57-63, 70-80, 83-86 or 90-106.

Claim 107 and its dependents (claims 108-109 and 113) claim a method for separating isomers by co-introducing a mixture of isomers in a first vehicle with a supercritical fluid in a particle formation vessel. Inoue's process does not involve *co-introducing* fluids in the manner required by the claims. Rather, he teaches that the SCF is simply passed over a static bulk of a mixture to be separated. Thus, Inoue's disclosure also fails to anticipate present claims 107-109

Appl. No. : 09/996,020
Filed : November 27, 2001

and 113, which require that an isomer mixture be separated by co-introducing it, in a fluid vehicle, with the precipitating SCF.

Claims 57-63, 70-80, 83-86, 90-109 and 113 were rejected under 35 USC 102(b) as anticipated by Sebastian (US Patent No. 5,196,575). Applicants respectfully traverse this rejection.

Sebastian's is a process for *extracting* materials so as to separate different components of a mixture, and relies on a SCF *dissolving* at least one of those components. Sebastian does not teach anything about producing *coated* particles, and so is not relevant to claims 57-63, 70-80, 83-86 or 90-106.

Further, Sebastian does not anticipate claims 107-113, which relate to the separation of isomer mixtures by co-introduction of the mixture in a first vehicle and a supercritical fluid. Sebastian does not describe or suggest the *co-introduction* into a particle formation vessel of a SCF and a mixture of isomers in a vehicle. In Sebastian's process, as in Inoue's, the mixture of isomers is charged into an extraction vessel (*not* a vessel in which particles are formed) and *then* the SCF solvent is flowed through it. The isomer mixture is not in a separate fluid vehicle.

Claims 57-63, 70-80, 83-86, and 90-106 were rejected under 35 USC 102(b) as anticipated by Murthy et al. (US Patent No. 4,737,384). Applicants respectfully traverse this rejection.

Murthy's coating process is very different to that of the present invention. It relies on the dissolution of a coating material in a solvent under supercritical conditions, followed by pressure reduction so as to precipitate the coating out of the solvent. It does not involve precipitating a solid out of a fluid vehicle using a *separate* SCF as an anti-solvent. Further, Murthy fails to disclose the formation of coated *particles*. Indeed, the substrates for which his process is intended appear to be larger-scale solid objects rather than individual particles of the type that could be carried in a flow of a fluid vehicle. Accordingly, claims 57-63, 70-80, 83-86 and 90-106, which are directed to the production of coated particulates are not anticipated by Murthy.

Appl. No. : 09/996,020
Filed : November 27, 2001

Claims 57-63, 70-80, 83-86, 91-99 and 101-106 were rejected under 35 USC 102(b) as anticipated by Cole et al. (US Patent No. 5,066,522). Applicants respectfully traverse this rejection.

Cole teaches a process for producing *liquid* coatings, not particles each of which comprises a substrate core and a coating layer. Again Cole provides no suggestions as to how one might form fine, coated solid particles for use for example as pharmaceuticals. The reference is not therefore relevant to present claims 57-63, 70-80, 83-86, 91-99 and 101-106.

In view of the above, the 35 USC 102(b) rejections are traversed and their reconsideration and withdrawal are believed to be in order.

The 35 USC 103 Rejections

Claims 114-123 were rejected under 102(b) as anticipated by or, in the alternative as obvious over Inoue, Sebastian, Murthy and Cole.

The present invention involves a very specific, and distinctive, form of fluid co-introduction. This gives improved control over the particulate product, and hence improved particle characteristics. It also allows more efficient solvent extraction, resulting in lower residual solvent levels in its products. The products of the invented process do *in fact* differ from those of the less controlled and less efficient prior art processes. It would not have been obvious, without the benefit of the teachings of the present invention, *how to achieve such properties*.

None of the cited art addresses the problem of preparing fine solid *particles* of the type which, like the products of the present invention, would be of use in pharmaceutical formulations. Murthy and Cole relate to coating but of much larger scale substrates; their processes would be highly unsuitable for the continuous production of tiny particles. They do not teach or suggest how one might control product characteristics such as particle size and morphology. Inoue and Sebastian teach isomer separation processes, but again these would be unsuitable for the continuous preparation of small particles. Further, there is no teaching or

Appl. No. : 09/996,020
Filed : November 27, 2001

suggestion with regard to the control of particle size and morphology.

The present invention provides a *single step*, continuous but highly controlled process for preparing such particles, the products of which have low residual solvent levels, high purity generally, small sizes and narrow size distributions. Such products were not taught or suggested by the references and thus are not anticipated or obvious thereover. Reconsideration and withdrawal of the 35 USC 102(b) and 103 (a) rejections are therefore respectfully requested.

CONCLUSION

In view of the above amendments and remarks, the claims are believed to be in condition for allowance. If it is believed that a telephonic interview would expedite prosecution of the present application, the Examiner is invited to telephone the undersigned attorney at the number below.

No fees are seen as being necessary in connection with this Response to the Office Action. However, the Commissioner is authorized to charge any fees in connection with this paper to Deposit Account No. 500348

Respectfully submitted,

Dated: February 4, 2004

By: Felissa H. Cagan

Felissa H. Cagan
Registration No. 35,089
(650) 631-3145